

K071542

Digital StereoLoc II

JUL - 5 2007

510(k) Summary of Safety Effectiveness

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87 (b)

Product Name: Digital StereoLoc II

Product Classification Name: Mammographic X-Ray System

Product Classification Code: 90 IZH **CFR Section:** 892.1710

Classification Panel: Radiology **Class** II

Manufacturer: Hologic, Inc.
36 Apple Ridge Road
Danbury, CT 06810 USA

Contact Person: Gail Yaeker-Daunis
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Date Prepared: May 4, 2007

Predicate Devices: K952210 Hologic Lorad StereoLoc II
K040884 Hologic Lorad DSM
K040125 Senographe Stereo General Electric Medical Systems

Device Description:

The Digital StereoLoc II is an optional accessory to the Selenia Full Field Digital Mammography System. It is attached to the Selenia to perform stereotactic biopsies and is composed of the following elements:

- The Biopsy Unit or Stage used for patient compression and vertical mounting of the biopsy needle.
- The SmartWindow control module for X and Y-axis motion control and Z-axis positioning guidance.
- DSM computer workstation and software for stereotactic targeting.

The breast is compressed between the compression paddle and the carbon fiber breast platform of the biopsy unit. The biopsy unit has its own manual compression mechanism

that is independent of the Selenia FFDM compression device. There are two compression knobs; one at each side of the biopsy unit. The Smart Window control module gets the Cartesian coordinates (X, Y, Z) of the target from the DSM workstation.

- X and Y motion is motorized. Controlled by the operator via the SmartWindow.
- Z-axis motion is manual and controlled by the operator.

Safety Features include:

- Automatic lockout of Biopsy Unit movement with C-Arm when patient is under compression.
- Automatic detection of biopsy unit and cables attached.
- Audible alert when switched from Stereo to C-Arm mode.
- Audible alert when Selenia compression device may interfere with stereo imaging movement.

How the Device Works:

Digital StereoLoc II for Selenia uses the Selenia detector for stereo image acquisition similar to the CCD camera used on the DSM system for the M-IV version of StereoLoc II (SLII). Stereotactic images are acquired at +/-15°. These stereo images are then automatically forwarded to the DSM Workstation for automatic calculation of the stereo coordinates and targeting of the lesion by the user (same as DSM operation with M-IV). The Compression Paddle and biopsy needle stage are the same as the StereoLoc II used with the Hologic Lorad M-IV, as are the X and Y-axis motion controllers. Both Compression and Z-axis movements are manually applied as with the M-IV. The stereo coordinates are then sent from the DSM Workstation to the Smart Window Control Module on the Digital StereoLoc LCD display (same as with StereoLoc II operation on M-IV). As with previous DSM Workstation versions, stereo images may be sent to PACS for archiving via DICOM protocol.

Indications for Use:

The Hologic Digital StereoLoc II is an optional accessory for the Selenia full field digital mammography system. It is designed to allow the accurate location of lesions in the breast in three dimensions, using information extracted from stereo tactic pairs of two-dimensional images. It is intended to provide guidance for interventional purposes (such as biopsy, pre-surgical localization or treatment devices).

Comparison With Predicate Devices:

The Hologic Digital StereoLoc II is substantially equivalent to the following devices:

K950220 Hologic Lorad StereoLoc II
K040884 Hologic Lorad DSM
K040125 Senographe Stereo General Electric Medical Systems

These devices are Mammographic X-Ray Systems which aid in the performance of breast biopsies and pre-surgical localization.

Summary of Testing

The Digital StereoLoc II System was tested by UL to IEC 60601-1 Medical Electrical Equipment Standards. The DSM Workstation complies with ACR/NEMA Digital Imaging Communications in Medicine version 3.0.

Hologic performs design control verification and validation tests under 21 CFR Part 820.

Conclusion

The Digital StereoLoc II principles of operation, clinical effectiveness, design, construction and materials are similar to existing marketed devices. This system poses no additional risk.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUL - 5 2007

Ms. Gail Yaeker-Daunis
Senior Regulatory Specialist
Hologic, Inc.
36 Apple Ridge Road
DANBURY CT 06810

Re: K071542
Trade/Device Name: Digital StereoLoc II
Regulation Number: 21 CFR 892.1710
Regulation Name: Mammographic x-ray system
Regulatory Class: II
Product Code: IZH
Dated: June 1, 2007
Received: June 5, 2007

Dear Ms. Yeaker-Daunis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.



Protecting and Promoting Public Health

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

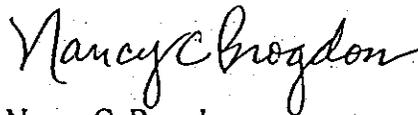
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) No.

Indications For Use

Device Name: **Digital StereoLoc II**

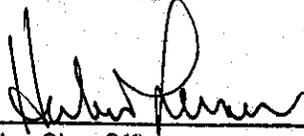
The Hologic Digital StereoLoc II is an optional accessory for the Selenia full field digital mammography system. It is designed to allow the accurate location of lesions in the breast in three dimensions, using information extracted from stereotactic pairs of two-dimensional images. It is intended to provide guidance for interventional purposes (such as biopsy, pre-surgical localization or treatment devices).

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
21 CFR 801.109

OR

Over-the-Counter Use



(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number

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